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UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff,	
v. MYLAN INC., MYLAN PHARMACEUTICALS INC. and MYLAN LABORATORIES LIMITED,) Civil Action No.: 14-cv-4508-JBS-KMW) REDACTED-FULL VERSION FILED) UNDER SEAL
Defendants.) Motion Return Date: Dec. 15, 2014) ORAL ARGUMENT REQUESTED

OTSUKA'S OPPOSITION TO MYLAN DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S COMPLAINT FOR LACK OF PERSONAL JURISDICTION

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I. INTRODUCTION

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka") respectfully submits this Opposition to Mylan's Motion to Dismiss Plaintiff's Complaint for Lack of Personal Jurisdiction. This Court should deny Mylan's Motion because Mylan is subject to this Court's specific jurisdiction. Mylan Pharmaceuticals Inc., acting in concert with Mylan Inc. and Mylan Laboratories Ltd. (collectively "Mylan"), has submitted an ANDA seeking FDA approval to market generic Abilify® (aripiprazole) tablets before the patents-at-issue expire, and this State is the likely destination of Mylan's infringing generic products.

Further, Mylan is subject to this Court's general jurisdiction. Mylan has expressly consented to this Court's jurisdiction through Mylan Pharmaceuticals Inc.'s admission in other judicial proceedings that "this Court has personal jurisdiction over Mylan by virtue of its presence in New Jersey and its continuous and systematic contacts with New Jersey." Mylan has also consented to jurisdiction by registering for business licenses in this State and retaining agents for service of process.

Mylan is also subject to jurisdiction in this State because Mylan maintains continuous and systematic contacts in this state such that New Jersey is a "home" forum for Mylan. For instance, Mylan maintains a presence in this State through at least three subsidiaries, generates substantial revenue in this State, retains employees in this state, applies for and receives Medicaid reimbursements in this state and regularly avails itself of the laws of New Jersey including in New Jersey courts.

Mylan cannot show that exercising jurisdiction here would be unfair or unreasonable, as litigating here would prevent significant waste of judicial resources given that this is just one of nineteen other pending related cases involving generic versions of Abilify® (aripiprazole) tablets, wherein no other defendant has contested personal jurisdiction.

For these reasons and the reasons set forth below, Otsuka respectfully requests that the Court deny Mylan's Motion to Dismiss.

II. FACTUAL BACKGROUND

A. This Litigation

Otsuka filed suit against Mylan on July 11, 2014, alleging that Mylan has infringed U.S. Patent Nos. 8,017,615 ("the '615 patent"), 8,580,796 ("the '796 patent"), 8,642,760 ("the '760 patent"), 7,053,092 ("the '092 patent") and U.S. Patent No. 8,642,600 ("the '600 patent") under 35 U.S.C. § 271(e)(2) by submitting an ANDA seeking FDA approval to market generic Abilify® (aripiprazole) tablets before the asserted patents expire. The '615 patent, the '796 patent and the '760 patent claim *inter alia*, novel crystalline forms of aripiprazole. The '092 patent and the '600 patent claim, *inter alia*, novel methods of treatment.

The Mylan defendants maintain a presence in this State though multiple New Jersey subsidiaries. For example, Mylan Inc. owns Agila Specialties Inc. and Mylan Specialty L.P., both located in New Jersey. Further, Mylan Laboratories Ltd. owns Mylan Laboratories Inc. (a.k.a. Matrix Laboratories Inc.), which is also located in New Jersey. *See* Ex. A, Mylan Inc. 10-K Annual Report Statement (filed Feb. 27, 2014) at 3-4 (indicating Mylan owns Agila Specialties Inc. and Mylan Specialty L.P.); Ex. B, Agila Specialties Inc. New Jersey Business Gateway Status Report; Ex. C, Mylan Specialty L.P. New Jersey Business Gateway Status Report; Ex. D, Mylan Laboratories Inc. Business Information Report at 3, 4 (indicating Mylan Laboratories Inc.'s parent company is Mylan Laboratories Ltd. and registered name is Matrix Laboratories, Inc.); Ex. E, Matrix Laboratories, Inc. New Jersey Business Gateway Status Report.

The Mylan parent companies that are defendants in this action have locations in various places. Specifically, Mylan Inc. is a corporation organized and existing under the laws of

Pennsylvania, having its principal place of business in Pennsylvania. Mylan Pharmaceuticals Inc., a wholly-owned subsidiary of Mylan Inc., is a corporation organized and existing under the laws of West Virginia, having its principal place of business in West Virginia.

Mylan Laboratories Ltd. is a corporation organized and existing under the laws of India, having its principal place of business in India. Mylan Laboratories Ltd. is a subsidiary of Mylan Inc. *See* D.I. 1 at ¶ 8; Ex. A, Mylan Inc. 10-K Annual Report Statement, filed Feb. 27, 2014, at 3.

Each of these defendant companies, however, operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States including in this judicial district. Indeed, Mylan Inc. describes Mylan Inc. and its subsidiaries as a company "with true vertical integration" and shares a website, holding itself and its subsidiaries out to the public as a single operational entity. *See* http://www.mylan.com/company/about-us (last accessed Dec. 1, 2014).

Regarding their respective roles in relation to the instant suit, Mylan Inc., the Pennsylvania entity, is the ultimate parent; Mylan Pharmaceuticals Inc., the West Virginia entity, submitted the ANDA to the FDA giving rise to this action; and Mylan Laboratories Ltd., the Indian entity, is believed to be the manufacturer and holds the drug master file ("DMF") of the aripiprazole active ingredient used in Mylan's infringing products. *See* D.I. 1 at ¶9; http://mylanlabs.in/our_businesses/~/media/mylan-india/pdf/ANNEX%204_Therapeutic%20 Segments%20-%20API.ashx (indicating Mylan Laboratories Ltd. manufacturers aripiprazole) (last accessed Dec. 1, 2014).

Otsuka properly brought suit against Mylan in this judicial district and this Court has personal jurisdiction over Mylan. Further, this case is one of nineteen related cases currently

pending before this Court. Of the thirty-eight defendants involved in these nineteen cases, only Mylan has contested personal jurisdiction.

B. Mylan's Continuous and Systematic New Jersey Contacts

Through its presence in this state and other actions and business activities in this State, Mylan maintains continuous and systematic contacts with New Jersey. As explained below, Mylan is a world-wide organization and conducts substantial business in this jurisdiction, is registered to do business in this jurisdiction, has employees in this jurisdiction, maintains registered agents in this jurisdiction, owns numerous subsidiaries and real properties located in this jurisdiction, and at least one Mylan defendant has appeared in proceedings in fifty-six or more times in this judicial district as the plaintiff or counterclaimant.

Otsuka has alleged in its Complaint that this judicial district is the likely destination of Mylan's generic products. D.I. 1 at ¶¶ 7-9. By Mylan's own admission, "[o]ne out of every 12 U.S. prescriptions dispensed, brand name or generic, is filled with a Mylan product." *See* http://www.mylan.com/businesses/generic-products (last accessed Dec. 1, 2014). Mylan "is a leading global pharmaceutical company which develops, licenses, manufactures, markets and distributes generic, branded generic and specialty pharmaceuticals," "had 324 ANDAs pending FDA approval" as of December 31, 2013, and "holds the number one ranking in the U.S. generics prescription market in terms of sales and the number two ranking in terms of prescriptions dispensed." *See* D.I. 1 at ¶ 7; *see also* Ex. A, Mylan, Inc.'s 10-K Report at 4. Accordingly, New Jersey is a likely destination for Mylan's generic products at issue in this case.

. Mot. at 11.

Tighe Decl. at ¶ 11.
Tighe Decl. at ¶ 7.
Mylan also maintains numerous business registrations in New Jersey.
both Mylan Inc. and Mylan Pharmaceuticals Inc.
are registered as drug Manufacturers and Wholesalers in New Jersey and are also registered with
the State of New Jersey Division of Revenue and Enterprise Services. Ex. F, Mylan Inc. New
Jersey Business Gateway Status Report; Ex. G, Mylan Pharmaceuticals Inc. New Jersey
Business Gateway Status Report. India-based Mylan Laboratories Ltd. is also registered as a
Wholesaler through its wholly-owned U.S. subsidiary, Mylan Laboratories Inc. D.I. 1 at ¶¶ 7-9.
Mylan Inc. and Mylan Pharmaceuticals Inc. maintain a registered agent for service of
process in New Jersey. Exs. F & G.
As noted above, Mylan Inc. and Mylan Laboratories Ltd. also own subsidiaries that are
located in New Jersey. Mylan Inc. owns Agila Specialties Inc. and Mylan Specialty L.P., both

As noted above, Mylan Inc. and Mylan Laboratories Ltd. also own subsidiaries that are located in New Jersey. Mylan Inc. owns Agila Specialties Inc. and Mylan Specialty L.P., both located in New Jersey, and Mylan Laboratories Ltd. owns Mylan Laboratories Inc. (a.k.a. Matrix Laboratories Inc.), which is also located in New Jersey. *See* Ex. A, Mylan Inc.'s 10-K Report at 3-4 (indicating Mylan owns Agila Specialties Inc. and Mylan Specialty L.P.); Ex. B, Agila Specialties Inc. Status Report; Ex. C, Mylan Specialty L.P. Status Report; Ex. D, Mylan Laboratories Inc. Business Information Report at 3, 4 (indicating parent company is Mylan Laboratories Ltd. and registered name is Matrix Laboratories, Inc.); Ex. E, Matrix Laboratories,

¹ A number of other Mylan subsidiaries are also registered to conduct business in New Jersey including Mylan Institutional LLC, Mylan Institutional Inc. and Mylan Specialty L.P.

Inc. Status Report. The subsidiary companies also hold drug registrations in New Jersey. For example, Mylan Specialty L.P. is registered in New Jersey as a drug Manufacturer and Wholesaler and Mylan Laboratories Inc. is registered in New Jersey as a drug Wholesaler.

Mylan, through its subsidiaries, owns real property in New Jersey. For example, Mylan Inc.'s subsidiary Mylan Specialty L.P. owns property located at 76 S. Orange Avenue, South Orange, NJ 07079 and Mylan Laboratories Ltd.'s subsidiary Mylan Laboratories, Inc. owns property located at 110 Allen Rd., Basking Ridge, NJ 07920.

Evidence of Mylan's continuous contacts with New Jersey further includes Mylan's active recruitment of participants for clinical drug trials in New Jersey. Ex. H, *Advair Diskus Local Equivalence Study in Asthma* (noting the "sponsor" and "responsible party" as Mylan Inc. and the "collaborator" as Mylan Pharma UK Ltd.); Ex. I, *A Comparison of Estradiol Vaginal Cream to Estrace*® *Cream in 350 Postmenopausal Females with Atrophic Vaginitis* (noting the "sponsor" and "responsible party" as Mylan Inc. and the "collaborator" as Mylan Pharmaceuticals). Mylan also provides New Jersey residents with information about HIV/AIDS planning. Ex. J, New Jersey HIV/AIDS Planning Group at 2, 3 (listing "Mylan/Bertek" under Prescription Assistance Programs). Additionally, Mylan Pharmaceuticals Inc. has received over \$26 million in Medicaid reimbursements for products sold to New Jersey residents since 2010. Ex. O, Summary of New Jersey Reimbursements for 2010-2014 for Mylan Pharmaceuticals Inc. Mylan also maintains an interactive website that can be reached from New Jersey. *See* http://www.mylan.com/ (last accessed Dec. 1, 2014).

Given Mylan's extensive and continuous contacts with this State, it is not surprising that Mylan is no stranger to New Jersey courts. In fifty-six cases or more, at least one Mylan defendant has served as plaintiff or counterclaimant. Ex. K, Summary of Mylan Litigation in

New Jersey. Mylan has also initiated suit. Id. (noting Mylan Inc. initiated at least two suits and Mylan Pharmaceutical Inc. has initiated at least two suits). And in at least fifty ANDA cases, at least one Mylan defendant consented to personal jurisdiction. Id. For example, in ANDA litigation similar to the present action, Mylan Pharmaceuticals Inc. explicitly admitted that "this Court has personal jurisdiction over Mylan by virtue of its presence in New Jersey and its continuous and systematic contacts with New Jersey." See Ex. L, Eli Lilly & Co. v. Actavis Elizabeth LLC, et al., 07-cv-3770-DMC (D.N.J. Sept. 5, 2007) (Plaintiffs' First Amended Complaint at ¶ 18 stating, "Upon information and belief, this Court has personal jurisdiction over Mylan by virtue of its presence in New Jersey and its continuous and systematic contacts with New Jersey."); Ex. M, Eli Lilly, 07-cv-3770-DMC (D.N.J. Oct. 1, 2007) (Mylan Pharmaceuticals Inc.'s Answer, Separate Defenses, and Counterclaims to Plaintiff's First Amended Complaint at ¶ 18 stating, "Mylan admits the allegations set forth in Paragraph 18 of the Complaint."); see also, e.g., Ex. N, Cephalon, Inc. v. Mylan Pharmaceutical, et al., 03-cv-01394-JCL-MF (D.N.J. June 9, 2003) (Answer to Complaint stating, "[Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc.] admits that it is subject to personal jurisdiction in this judicial district.").

III. ARGUMENT

A. Legal Standard

In assessing personal jurisdiction, a Court first confirms that the New Jersey long-arm statute permits jurisdiction, and then confirms that exercising jurisdiction would comport with due process. *FlagHouse, Inc. v. ProSource Development, Inc.*, 528 Fed. Appx. 186, 188-89 (3d Cir. 2013); *see also* N.J. R. Ct. 4:4-4. In New Jersey, however, the long-arm statute "provides for personal jurisdiction coextensive with that allowed by the United States Constitution." *Flaghouse*, 528 Fed. Appx. at 189; *see also Colvin v. Van Wormer Resorts, Inc.*, 417 Fed. Appx. 183, 186 (3d Cir. 2011). Thus the inquiry collapses into the due process inquiry.

"[D]ue process requires only that in order to subject a defendant to a judgment in personam, if he be not present within the territory of the forum, he have certain minimum contacts with it such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." *International Shoe Co. v. State of Washington*, 326 U.S. 310, 316 (1945) (internal quotations omitted). Under this doctrine, courts can exercise either general or specific jurisdiction over a defendant. *LSI Industries Inc. v. Hubbell Lighting, Inc.*, 232 F.3d 1369, 1375 (Fed. Cir. 2000) ("Under the 'minimum contacts' test, a defendant may be subject to either specific jurisdiction or general jurisdiction."). A court can exercise general jurisdiction over a defendant who has "continuous and systematic" contacts with the forum state and does not require that the cause of action arise out of contacts with the forum state. *Helicopteros Nacionales de Colombia v. Hall*, 466 U.S. 408, 415-16 (1984). In contrast, specific jurisdiction exists where "the defendant has 'purposefully directed' his activities at residents of the forum, and the litigation results from alleged injuries that 'arise out of or relate to' those activities." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985) (internal citations omitted).

The Court of Appeals for the Federal Circuit considers three factors relevant to specific jurisdiction: (1) whether the defendant purposefully directed activities at the residents of the forum; (2) whether the claims relate to the those activities; and (3) whether the assertion of personal jurisdiction is reasonable and fair. *See Nuance Communications, Inc. v. Abbyy Software House*, 626 F.3d 1222, 1231 (Fed Cir. 2010). The plaintiff must establish the first two factors are met, at which point the defendant can attempt to show that jurisdiction would be unreasonable under the third factor. *See id.* The Supreme Court has advised that the third factor applies only sparingly, and to defeat jurisdiction, a defendant must "present a compelling case that the presence of some other considerations would render jurisdiction unreasonable." *Id.*

Ultimately, as stated above, the defendant should have minimum contacts with the forum such that exercising jurisdiction "does not offend traditional notions of fair play and substantial justice." *International Shoe*, 326 U.S. at 316.

As explained below, this Court should exercise both specific and general jurisdiction over Mylan.

B. This Court Should Exercise Specific Jurisdiction Over Mylan

Mylan is subject to specific jurisdiction in New Jersey. The submission of Mylan's ANDA to the FDA by Mylan Pharmaceutical Inc., who was acting in concert with Mylan Inc. and Mylan Laboratories Ltd., is a real act with actual consequences. See Zeneca Ltd. v Mylan Pharmaceuticals, Inc., 173 F.3d 829, 833-834 (Fed. Cir. 1999). Not only has Mylan infringed the asserted patents, but Mylan is seeking approval to market its generic products in New Jersey. As stated above, Mylan has admitted that "[o]ne out of every 12 U.S. prescriptions dispensed, brand generic, is filled with Mylan product." See name or http://www.mylan.com/businesses/generic-products (last accessed Dec. 1, 2014). Mylan has also admitted that it "is a leading global pharmaceutical company which develops, licenses, manufactures, markets and distributes generic, branded generic and specialty pharmaceuticals," "had 324 ANDAs pending FDA approval" as of December 31, 2013, and "holds the number one ranking in the U.S. generics prescription market in terms of sales and the number two ranking in terms of prescriptions dispensed." See D.I. 1 at ¶ 7; see also Ex. A Mylan, Inc.'s 10-K Report at 4.

Mot. at 11. But

Mylan's argument fails because the fact that it seeks

does not diminish the fact that it is continuing to seek approval of its ANDA so that it can market in New Jersey. Indeed, Mylan has already set the wheels in motion for marketing its generic tablets. The vertically integrated Mylan defendants have a network of businesses set up to handle Mylan's pharmaceutical sales across the country, including in New Jersey; the Mylan defendants are licensed and registered to distribute pharmaceuticals in New Jersey; Mylan Inc. and Mylan Pharmaceuticals Inc. have registered agents for process service; and Mylan maintains related business locations in New Jersey. Mylan is thus purposefully directing activities in this forum and will continue to do so. This Court therefore has specific jurisdiction. See Sandoz, Inc. v. Pfizer, Inc., Civil Action No. 09-cv-02457-CMA-MJW, 2010 WL 502727, at *3 (D. Colo. Feb. 8, 2010) (finding Delaware could likely exercise personal jurisdiction over generic manufacturing defendant because the defendant was licensed to sell generic pharmaceuticals in the state and had not contested jurisdiction in other unrelated cases in the state before, among other reasons).

Another court in this circuit has expressly found Mylan Pharmaceuticals Inc. subject to specific personal jurisdiction on almost identical facts as here. *AstraZeneca AB v. Mylan Pharmaceuticals, Inc.*, Civil Action No. 14-696-GMS, 2014 WL 5778016, at *6-8 (D. Del. Nov. 5, 2014) (Sleet, J.). There, Mylan Pharmaceuticals Inc. challenged Delaware's exercise of personal jurisdiction, but the court found that because Mylan Pharmaceuticals Inc.'s contacts with Delaware were not "illusory," it could properly exercise specific jurisdiction. *Id.* at *7. Although "ANDA litigation is unlike other patent infringement litigation" in that the "injury is abstract, making it difficult to point to a location out of which the injury 'arises' for jurisdictional purposes[,]" (*id.* at *6), in patent law, "the injury occurs at the place where the infringing activity directly impacts on the interests of the patentee," which here, includes New Jersey. *Trintec*

Industries, Inc. v. Pedre Promotional Products, Inc., 395 F.3d 1275, 1280 (Fed. Cir. 2005) (internal quotation marks and citation omitted). Otsuka has chosen this forum as the location for all nineteen pending Abilify[®] tablets cases and resolving these cases in New Jersey will promote judicial economy and avoid the possibility of inconsistent outcomes. Further, Mylan's significant contacts with this forum can hardly be considered "illusory."

The only issue remains whether Mylan can overcome the heavy burden to show that exercising jurisdiction in New Jersey is somehow not reasonable or unfair. *See Nuance*, 626 F.3d at 1231. Relevant factors include "the burden on the defendant, the forum State's interest in adjudicating the dispute, the plaintiff's interest in obtaining convenient and effective relief, the interstate judicial system's interest in obtaining the most efficient resolution of controversies, and the shared interest of the several States in furthering fundamental substantive social policies. *Burger King*, 471 U.S. at 477 (quotation marks omitted).

No factor weighs against jurisdiction here. As an initial matter, the Mylan defendants should expect to be sued in New Jersey given that they maintain licenses here, Mylan Inc. and Mylan Pharmaceuticals maintain an agent for service of process here, and the Mylan defendants conduct significant business here. Further, as the court in *AstraZeneca* held, "patent litigation is an integral part of a generic drug company's business" thus Mylan, which holds the number one ranking in the U.S. generics prescription market, cannot plausibly argue that it could not "reasonably anticipate being haled into court" in New Jersey. *See Astra Zeneca*, 2014 WL 5778016, at *7 (citing *Burger King*, 471 U.S. at 474 (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 295 (1980)). In that vein, it is not surprising that Mylan itself is very familiar with New Jersey courts. As of December 1, 2014, at least one Mylan defendant has been involved in fifty-six cases or more in New Jersey where it was either the plaintiff or

counterclaimant, initiating suit in four of those cases, and thus availing itself of New Jersey's laws. Ex. K, Summary of Mylan Litigation. As stated above, in at least fifty ANDA-related cases, at least one Mylan defendant expressly consented to personal jurisdiction. *Id*.

Exercising jurisdiction over Mylan is also warranted because there are nineteen related cases currently pending before this Court, and resolving "these cases in a single district will promote judicial economy and avoid the possibility of inconsistent outcomes." *See AstraZeneca*, 2014 WL 5778016 at *8. This Court should deny Mylan's motion.

C. This Court Should Also Exercise General Jurisdiction Over Mylan

1. Mylan Consented to Personal Jurisdiction in New Jersey

It is well settled that a party can consent to personal jurisdiction of a court. *Insurance* Corp. of Ireland, Ltd. v. Compagnie des Bauxites de Guinee, 456 U.S. 694, 702-04 (1982) ("Because the requirement of personal jurisdiction represents first of all an individual right, it can, like other such rights, be waived."). Here, Mylan has expressly consented to personal jurisdiction repeatedly. For example, Mylan Pharmaceuticals Inc., the ANDA-filer in this case, admitted in 2007 in another ANDA-related case that "this Court has personal jurisdiction over Mylan by virtue of its presence in New Jersey and its continuous and systematic contacts with New Jersey." Ex. L, Eli Lilly, 07-cv-3770-DMC (D.N.J. Sept. 5, 2007) (Plaintiffs' First Amended Complaint at ¶ 18 (emphasis added)); Ex. M, Eli Lilly, 07-cv-3770-DMC (D.N.J. Oct. 1, 2007) (Mylan Pharmaceuticals Inc.'s Answer, Separate Defenses, and Counterclaims to Plaintiff's First Amended Complaint at ¶ 18). In at least fifty other ANDA cases, at least one Mylan defendant has similarly consented to personal jurisdiction in New Jersey. See, e.g., Ex. L. Ex. M and Ex. N, Cephalon, Inc. v. Mylan Pharmaceutical, et al., 03-cv-01394-JCL-MF (D.N.J. June 9, 2003) (Answer to Complaint stating, "Mylan admits that it is subject to personal jurisdiction in this judicial district"). In fifty-six cases or more, at least one Mylan defendant has

served as plaintiff or counterclaimant in this jurisdiction. Ex. K, Summary of Mylan Litigation in New Jersey. In four cases, at least one Mylan defendant initiated suit. *Id*.

The Mylan defendants have also consented to personal jurisdiction in this State by registering to do business in New Jersey. And Mylan Inc. and Mylan Pharmaceuticals Inc. maintain an agent for service of process in New Jersey. Mylan attempts to skirt this issue by citing 4th Circuit law from 1971 (Mot. at 5-6), but according to the Third Circuit and the District Court of New Jersey, registering to do business and maintaining an agent for service of process in New Jersey is consent to general jurisdiction. Bane v. Netlink, Inc., 925 F.2d 637, 640 (3d Cir. 1991) ("We need not decide whether authorization to do business in Pennsylvania is a 'continuous and systematic' contact with the Commonwealth for purposes of the dichotomy between 'general' and 'specific' jurisdiction because such registration by a foreign corporation carries with it consent to be sued in Pennsylvania courts."); Sadler v. Hallsmith SYSCO Food Services, No. 08-4423-RBK/JS, 2009 WL 1096309, at *2 (D.N.J. Apr. 21, 2009); Koff v. Brighton Pharmaceutical, Inc., 709 F. Supp. 520, 527 (D.N.J. 1988) ("Since the very purpose of designating such an agent was to make it possible for [defendant] to be sued for causes of action arising from or related to its New Jersey activities, [defendant] cannot claim that it could not reasonably have foreseen being haled into a New Jersey court by virtue of a contract to buy a New Jersey corporation from New Jersey residents."); X-L Liquors v. Taylor, 17 N.J. 444, 452-53 (N.J. 1955) (exercising jurisdiction over foreign corporation that had designated an authorized agent for service of process); see also Sternberg v. O'Neil, 550 A.2d 1105, 1009, 1111-12 (Del. 1988) (finding foreign corporation that appointed registered agent for the service of process consented to general jurisdiction) (citing Neirbo Co. v. Bethlehem Shipbuilding Corp., 308 U.S.

165, 170-71 (1939); Pennsylvania Fire Insurance. Co. of Philadelphia v. Gold Issue Mining & Milling Co., 243 U.S. 93, 95 (1917)).

Mylan cites no controlling authority that changes the Third Circuit's analysis in Bane, that is, appointment of an agent for service of process is consent to jurisdiction. Bane has been followed in New Jersey by Sadler. In Sadler, the court found that defendants' compliance with New Jersey's registration statute provided consent to general jurisdiction. 2009 WL 1096309, at *1 ("[Defendant] concedes that it is registered to do business in New Jersey and has a registered agent for service of process in New Jersey Therefore, [defendant] has consented to being sued in New Jersey[,]"). Under New Jersey's registration statute, "Every corporation organized for any purpose under any general or special law of this State and every foreign corporation authorized to transact business in this State shall continuously maintain a registered office in this State, and a registered agent having a business office identical with such registered office." N.J.S.A. 14A:4-1 (emphasis added). The Sadler court expressly considered, and rejected, the premise that *Bane's* holding is limited to the particulars of Pennsylvania's registration statute. Indeed, the court found "that the difference between the wording of the Pennsylvania and New Jersey statutes is not determinative." 2009 WL 1096309, at *2 (citing and quoting Litton Industrial Systems, Inc. v. Kennedy Van Saun Corp., 283 A.2d 551, 556 (N.J. Super. Ct. Law Div. 1971) ("[D]efendant's designation of an agent for the service of process under N.J.S.A. 14A:4-1 amounted to a consent by defendant to be sued in the state courts of New Jersey ")). It is undisputed that

Mylan is registered to conduct pharmaceutical-related business within the State of New Jersey. Tighe Decl. at ¶ 9; Exs. B, C, E, F & G (Status Reports); D.I. 1 at ¶ 7-9. Mylan Inc. and Mylan Pharmaceuticals Inc. maintain a registered agent for service of process in New

Jersey. Exs. F & G (Status Reports). Thus, Mylan has consented to jurisdiction in New Jersey, and "the Court need not engage in an analysis of [defendants'] contacts with the state." *Sadler*, 2009 WL 1096309, at *2.

Where there is consent, this ends the jurisdictional inquiry. *Id.* The holding in *Bane* is supported by the Supreme Court's analysis of jurisdiction based on consent. In *Pennsylvania Fire*, a unanimous Supreme Court held that a Missouri court could constitutionally exercise personal jurisdiction over a foreign corporation even though its only apparent contact with Missouri was registering to do business and appointing an agent for service of process. 243 U.S. at 95. Exercising jurisdiction "did not deprive the defendant of due process of law even if it took the defendant by surprise[.]" *Id.* And the Supreme Court reaffirmed this holding in *Neirbo*, finding a constitutional exercise of jurisdiction where "service on the agent shall give jurisdiction of the person[,]" because designating an agent was "part of the bargain" by which the foreign corporation enjoyed the freedom to conduct business in New York. 308 U.S. at 175. While Mylan suggests that *Pennsylvania Fire* is no longer good law (Mot. at 7-8), nothing in the Court's post-*Pennsylvania Fire* jurisprudence changes the well-settled law regarding general jurisdiction based on consent.

Mylan relies on *Daimler AG v. Bauman*, 134 S.Ct. 746 (2014) and *Goodyear Dunlop Tires Operations*, S.A. v. Brown, 131 S. Ct. 2846 (2011), to say that, notwithstanding that Mylan is registered to do business in this State and Mylan Inc. and Mylan Pharmaceuticals Inc. maintain an agent for service of process, it is not "at home" here and thus cannot be subject to jurisdiction here. Mot. at 3-6 (citing *Goodyear*, 131 S. Ct. at 2851). Unlike Mylan, however, the corporation in *Goodyear* was not registered to do business in the contested forum. 131 S. Ct. at 2852 ("In contrast to the parent company, Goodyear USA, which does not contest the North Carolina

courts' personal jurisdiction over it, petitioners are not registered to do business in North Carolina.").

Mylan's reliance on *Daimler* is equally misplaced. In *Daimler*, the plaintiff asserted California had jurisdiction over Daimler AG through its contacts with an independent "indirect subsidiary" MBUSA. 134 S. Ct. at 752. While Mylan may point to *Daimler's* holding that even if the Court "were to assume that MBUSA is at home in California, and further to assume MBUSA's contacts are imputable to Daimler, there would still be no basis to subject Daimler to general jurisdiction in California," there is no indication that Daimler AG was registered to do business, appointed an agent for service or consented to suit in the forum as Mylan has done here in this State. In both *Goodyear* and *Daimler*, the Supreme Court implicitly recognized that any analysis of "minimum contacts" applies only to those corporations that have "not consented to suit in the forum." *Goodyear*, 131 S. Ct. at 2856; *Daimler*, 134 S. Ct. at 755-56 (referring to *Perkins v. Benguet Consolidated Mining Co.*, 72 S. Ct. 413 (1952), as the "textbook case of general jurisdiction appropriately exercised over a foreign corporation that has not consented to suit in the forum") (emphasis added).

Mylan similarly misapplies isolated New Jersey cases in arguing that its business activities in this State are not the equivalent of consent. Mot. at 9. For example, *Agbottah v. Orange Lake Country Club, Inc.*, is distinguishable from the present case in that the defendant there apparently had a registration in New Jersey "to conduct telemarketing sales," but it had no "agents, property, records, or other contacts" in New Jersey. Civil Action No. 12-1019, 2012 WL 2679440, at *3-4 (D.N.J. July 6, 2012). *Kubin v. Orange Lake Country Club, Inc.* is also inapplicable where the court made expressly clear that the defendant had no "employees, officers, agents or records in New Jersey." Civil Action No. 10-1643 (FLW), 2010 WL

3981908, at *2 (D.N.J. Oct. 8, 2010). Similarly, *Smith v. S7S Dundalk Engineering Works, Ltd.* is inapplicable because the court noted that the defendants had no "property, bank or credit accounts, employees, officers, agents or records in New Jersey[.]" 139 F. Supp. 2d 610, 619 (D.N.J. 2001). *Atkinson & Mullen Travel Inc. v. New York Apple Tours Inc.* is also inapplicable where the court noted that the defendant "employ[ed] no agents in New Jersey." Civil Action No. 97-4460, 1998 WL 750355, at *2 (D.N.J. Sept. 16, 1998). By contrast, as explained above, Mylan is a world-wide organization and conducts substantial business in this jurisdiction. The Mylan defendants are licensed to do business in this jurisdiction,

Mylan Inc. and Mylan Pharmaceuticals Inc. maintain registered agents in this jurisdiction, and Mylan Inc. and Mylan Laboratories Ltd. own subsidiaries and real property located in this jurisdiction, and at least one Mylan defendant has appeared in proceedings fifty-six or more times in this judicial district as the plaintiff or counterclaimant. Thus Mylan has effectively consented to jurisdiction in this district.

Mylan also cites other non-authoritative cases from the Fourth, Fifth and Seventh Circuits suggesting that a party does not consent to jurisdiction where it has registered to do business. Mot. at 7. However, none of these cases alter the controlling precedent in *Bane* establishing consent-based jurisdiction. 925 F.2d at 641 ("We hold that because [defendant] was authorized to do business in Pennsylvania, it was subject to the exercise of personal jurisdiction by Pennsylvania courts[.]"). Indeed, other circuits follow the reasoning in *Bane* and find consent to jurisdiction on similar facts. *STX PanOcean (UK) Co., Ltd. v. Glory Wealth Shipping Pte Ltd.*, 560 F.3d 127, 131 (2d Cir. 2009) ("It is well-settled under New York law that registration under [New York's foreign corporation registration statute] subjects foreign companies to personal

jurisdiction in New York.") (internal citations omitted); *Knowlton v. Allied Van Lines, Inc.*, 900 F.2d 1196, 1200 (8th Cir. 1990) (finding consent to general jurisdiction because "[a]ppointment of a registered agent for service is . . . a traditionally recognized and well-accepted species of general consent"); *Holloway v. Wright & Morrissey, Inc.*, 739 F.2d 695, 697 (1st Cir. 1984) ("It is well-settled that a corporation that authorizes an agent to receive service of process in compliance with the requirements of a state statute, consents to the exercise of personal jurisdiction in any action that is within the scope of the agent's authority.").

Accordingly, nothing supports deviating from the controlling precedent in *Bane*. For at least the reasons explained above, Mylan has consented to jurisdiction in this State and thus is subject to this Court's jurisdiction.

2. Mylan's Continuous and Systematic Contacts with New Jersey Also Support General Jurisdiction

This Court may exercise general jurisdiction over Mylan because its contacts with New Jersey "are so continuous and systematic as to render [it] essentially at home in the forum State." Daimler, 134 S. Ct. at 754 (quoting Goodyear, 131 S. Ct. at 2851). Nothing in the Supreme Court's Daimler decision changes the fact that Mylan is at home in New Jersey. The facts in Daimler are distinguishable—there, the plaintiffs wanted a California court to hold Daimler AG (a German company) vicariously liable for its Argentinean counterpart's alleged collaboration with Argentinean officials' actions during Argentina's "Dirty War." 134 S. Ct. at 751-52. The only connection to California was the business dealings of MBUSA, an indirect and independent subsidiary company of Daimler AG. Id. The Supreme Court therefore held that these attenuated connections did not permit jurisdiction over the German-based Daimler AG, because neither MBUSA nor Daimler AG were "at home" in California. Id. at 760.

In contrast, Mylan has made a home of New Jersey. As stated above, the Mylan defendants maintain active registrations in New Jersey and use them to conduct pharmaceutical-related business. Mylan Inc. and Mylan Pharmaceuticals Inc. are both registered corporations with the State of New Jersey and maintain a registered agent for service of process in this State.

Exs. F & G.
Tighe Decl. ¶ 9.

Further, Mylan maintains a significant corporate presence in New Jersey through multiple New Jersey subsidiaries. As noted, Mylan Inc. owns Agila Specialties Inc. and Mylan Specialty L.P., both located in New Jersey. Also, Mylan Laboratories Ltd. owns Mylan Laboratories Inc. (a.k.a. Matrix Laboratories Inc.), which is also located in New Jersey. Exs. B, C, E.

Tighe Decl. ¶ 11. Moreover,

Mylan Inc. actively recruits participants for drug studies in New Jersey and provides HIV/AIDS information to New Jersey residents. Exs. H, I, J. Mylan maintains an interactive website that can be reached from New Jersey. In addition, publically available Medicaid reimbursement data shows that Mylan Pharmaceuticals Inc. has received over \$26 million in Medicaid reimbursements for products sold to New Jersey residents since 2010. Ex. O, Summary of New Jersey Reimbursements for 2010-2014 for Mylan Pharmaceuticals Inc. Mylan is fully present and doing business in New Jersey, just like a resident corporation. *See LSI*, 232 F.3d at 1375 ("Based on [defendant's] millions dollars of sales of lighting products in Ohio over the past several years and its broad distributorship network in Ohio, we find that [defendant] maintains

'continuous and systematic' contacts with Ohio. Therefore [defendant] is subject to general

jurisdiction in Ohio under the Due Process Clause.").

Evidencing Mylan's continuous and systematic business activities in this State, Mylan is

no stranger to New Jersey courts. There have been at least fifty-six cases where at least one

Mylan defendant has been a plaintiff or a counterclaimant. Ex. K. In four cases, at least one

Mylan defendant initiated suit. Id. In at least fifty prior ANDA cases, at least one Mylan

defendant consented to jurisdiction. Id. Litigation is an integral part of a generic company's

business, and thus Mylan's extensive litigation activities in this state further establish that it has

purposefully availed itself of the benefits and protections of the forum.

New Jersey is certainly "home" for Mylan, and this court should accordingly deny

Mylan's motion.

CONCLUSION IV.

For at least the foregoing reasons, this Court should deny Mylan's motion to dismiss.

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Respectfully submitted,

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